



State of Utah

GARY R. HERBERT
Governor

SPENCER J. COX
Lieutenant Governor

Department of Environmental Quality

Alan Matheson
Executive Director

DIVISION OF AIR QUALITY
Bryce C. Bird
Director

DAQE-AN103770010-18

November 15, 2018

Robert Partner
BD Medical
9450 South State Street
Sandy, UT 84070

Dear Mr. Partner:

Re: Approval Order: Modification to Approval Order DAQE-AN103770009-16 to Increase
Production Lines and Replace Equipment
Project Number: N10377-0010

The attached document is the Approval Order for the above-referenced project. Future correspondence on this Approval Order should include the engineer's name as well as the DAQE number as shown on the upper right-hand corner of this letter. The project engineer for this action is Ana Williams, who may be reached at (801) 536-4153.

Sincerely,

Bryce C. Bird
Director

BCB:AW:sa

cc: Salt Lake Valley Health Department

STATE OF UTAH

Department of Environmental Quality

Division of Air Quality

**APPROVAL ORDER: Modification to Approval Order
DAQE-AN103770009-16 to Increase Production
Lines and Replace Equipment**

**Prepared By: Ana Williams, Engineer
Phone: (801) 536-4153
Email: anawilliams@utah.gov**

APPROVAL ORDER NUMBER

DAQE-AN103770010-18

Date: November 15, 2018

BD Medical

Source Contact:

**Robert Partner, Safety and Environmental Manager
Phone: (801) 565-2507
Email: bob_partner@bd.com**

**Bryce C. Bird
Director**

Abstract

BD Medical is an existing medical device fabricating and drug manufacturing plant located in Sandy, Salt Lake County. BD Medical has requested a modification to AO DAQE-AN103770009-16 dated December 15, 2016, to add five (5) new product lines, add a new regenerative thermal oxidizer to control three (3) of the new product lines, and replace a proposed fire pump engine with a new engine. The addition of the five (5) new product lines will increase the VOC emission limitations.

Salt Lake County is a NAA of the NAAQS for PM₁₀, PM_{2.5}, SO₂, and ozone, and an attainment area for all other criteria pollutants. NSPS (40 CFR 60 Subpart A and IIII) and MACT (40 CFR 63 Subparts A, O, and ZZZZ) regulations apply to this source. NESHAP (40 CFR 61) regulations and Title V of the 1990 CAA do not apply to this source.

The PTE, in TPY, will change as follows: NO_x = +0.02, CO = +0.05, VOC = +2.77, and CO_{2e} = +88.00

The PTE, in TPY, will be as follows: PM₁₀ = 1.31, PM_{2.5} (subset of PM₁₀) = 1.31, NO_x = 18.18, SO₂ = 0.81, CO = 13.19, VOC = 25.20, HAPs = 2.09, and CO_{2e} = 20,270

This air quality AO authorizes the project with the following conditions and failure to comply with any of the conditions may constitute a violation of this order. This AO is issued to, and applies to the following:

Name of Permittee:

BD Medical
9450 South State Street
Sandy, UT 84070

Permitted Location:

BD Medical
9450 South State Street
Sandy, UT 84070

UTM coordinates: 424,505 m Easting, 4,492,433 m Northing, UTM Zone 12
UTM Datum: NAD27

SIC code: 3841 (Surgical & Medical Instruments & Apparatus)

Section I: GENERAL PROVISIONS

- I.1 All definitions, terms, abbreviations, and references used in this AO conform to those used in the UAC R307 and 40 CFR. Unless noted otherwise, references cited in these AO conditions refer to those rules. [R307-101]
- I.2 The limits set forth in this AO shall not be exceeded without prior approval. [R307-401]
- I.3 Modifications to the equipment or processes approved by this AO that could affect the emissions covered by this AO must be reviewed and approved. [R307-401-1]
- I.4 All records referenced in this AO or in other applicable rules, which are required to be kept by the owner/operator, shall be made available to the Director or Director's representative upon request, and the records shall include the two (2)-year period prior to the date of the request. Unless otherwise specified in this AO or in other applicable state and federal rules, records shall be kept for a minimum of two (2) years. [R307-401-8]
- I.5 At all times, including periods of start-up, shutdown, and malfunction, owners and operators shall, to the extent practicable, maintain and operate any equipment approved under this AO, including associated air pollution control equipment, in a manner consistent with good air pollution control practice for minimizing emissions. Determination of whether acceptable

operating and maintenance procedures are being used will be based on information available to the Director which may include, but is not limited to, monitoring results, opacity observations, review of operating and maintenance procedures, and inspection of the source. All maintenance performed on equipment authorized by this AO shall be recorded. [R307-401-4]

- I.6 The owner/operator shall comply with UAC R307-107. General Requirements: Breakdowns. [R307-107]
- I.7 The owner/operator shall comply with UAC R307-150 Series. Emission Inventories. [R307-150]
- I.8 The owner/operator shall submit documentation of the status of construction or modification to the Director within 18 months from the date of this AO. This AO may become invalid if construction is not commenced within 18 months from the date of this AO or if construction is discontinued for 18 months or more. To ensure proper credit when notifying the Director, send the documentation to the Director, attn.: NSR Section. [R307-401-18]

Section II: SPECIAL PROVISIONS

II.A The approved installations shall consist of the following equipment:

- II.A.1 **BD Medical**
Medical Device Manufacturing Plant
- II.A.2 **Ethylene Oxide Sterilization Process**
Six (6) Sterilization Chambers
Six (6) Aeration Rooms
One (1) Desorption Tower
One (1) Concentration Balancing Tank
One (1) Lesni Catalytic Oxidizer
MACT Applicability: Subpart O
- II.A.3 **Alliance Thermal Incinerator**
Fuel Type: Natural Gas or Process Off-gas
Heating Capacity: Less than 5 MMBtu/hr
Processes Controlled:
Two (2) Push Button Blood Collection Manufacturing Lines
Three (3) Nexiva Catheter Zone 3 Manufacturing Lines*
Three (3) Autoguard Catheter Manufacturing Lines*

*One new manufacturing line each
- II.A.4 **Lesni Regenerative Thermal Oxidizer**
Fuel Type: Natural Gas or Process Off-gas
Heating Capacity: Less than 5 MMBtu/hr
Processes Controlled:
Eight (8) Autoguard Catheter Manufacturing Lines
Three (3) Nexiva Manufacturing Lines*

*One new manufacturing line

- II.A.5 **Alliance Boxidizer Regenerative Thermal Oxidizer***
Fuel Type: Natural Gas or Process Off-gas
Heating Capacity: Less than 5 MMBtu/hr
Processes Controlled:
 Three (3) Autoguard Catheter Manufacturing Lines*
- *New equipment and manufacturing lines
- II.A.6 **Two (2) Boilers**
Fuel Type: Natural Gas
Heating Capacity: 5.9 MMBtu/hr each
Controls: Low-NO_x Burners
- II.A.7 **Two (2) Fire Suppression System Pump Engines**
Fuel Type: Diesel
Rated: One (1) 310 hp engine and one (1) 157 hp engine*
NSPS Applicability: NSPS Subpart IIII (Applies to the 157 hp engine)
MACT Applicability: Subpart ZZZZ (Applies to both engines)
- *New equipment
- II.A.8 **Three (3) Emergency Power Generator Engines**
Fuel Type: Diesel
Rated: 939 hp, 900 hp, 465 hp
MACT Applicability: Subpart ZZZZ
- II.A.9 **Miscellaneous Operations and Equipment Items**
Various Quality Assurance and Research and Development Laboratories
Five (5) Storage Tanks (diesel storage service)
Various Natural Gas-Fired Boilers rated less than 5 MMBtu/hr each
Various Natural Gas-Fired HVAC Units rated less than 5 MMBtu/hr each
Ten (10) Cooling Towers
Various Forklifts and Yard Tractor
Parking Area
- II.A.10 **Six (6) Electric Silicone Post Curing Ovens***
Emission Control Technology:
Electrostatic Precipitator (exhaust pretreatment on one (1) curing oven)
Mist Eliminator
Condensate Knockout Chamber
Coalescing Filter
HEPA Filter
- *One oven is new equipment.
- II.A.11 **Cleaning Oven**
Fuel Type: Natural Gas
Heating Capacity: 3.0 MMBtu/hr
Emission Control Technology:
Thermal Oxidation (part of the proposed cleaning oven)

II.B Requirements and Limitations

II.B.1 Medical Device Manufacturing Plant

- II.B.1.a The owner/operator shall not allow visible emissions from the following emission points to exceed the following values:
- A. Diesel-fired emergency generator engines and fire pump engines - 20% opacity
 - B. All other stationary point or fugitive emissions sources - 10% opacity
- [R307-401-8]
- II.B.1.a.1 Opacity observations of emissions from stationary sources shall be conducted according to 40 CFR 60, Appendix A, Method 9. [R307-401-8]
- II.B.1.b The owner/operator shall not exceed a total ethylene oxide consumption limit of 456,000 pounds per rolling 12-month period. [R307-401-8]
- II.B.1.b.1 To determine compliance with a rolling 12-month total, the owner/operator shall calculate a new 12-month total by the 20th day of each month using data from the previous 12 months. Ethylene oxide consumption shall be determined based on inventory and purchase records. [R307-401-8]
- II.B.1.c The owner/operator shall not operate each emergency generator or fire pump engine on site for more than 100 hours per rolling 12-month period during non-emergency situations. There is no time limit on the use of the engines during emergencies. [40 CFR 60 Subpart IIII, 40 CFR 63 Subpart ZZZZ, R307-401-8]
- II.B.1.c.1 To determine compliance with a rolling 12-month total, the owner/operator shall calculate a new 12-month total by the 20th day of each month using data from the previous 12 months. Records documenting the operation of each emergency generator or fire pump engine shall be kept in a log and shall include the following:
- A. The date the emergency generator or fire pump engine was used
 - B. The duration of operation in hours
 - C. The reason for the emergency generator or fire pump engine usage
- [R307-401-8]
- II.B.1.c.2 To determine the duration of operation, the owner/operator shall install a non-resettable hour meter for each emergency generator and fire pump engine. [40 CFR 60 Subpart IIII, 40 CFR 63 Subpart ZZZZ, R307-401-8]
- II.B.1.d The sulfur content of diesel fuel burned in the stationary diesel engines on site shall not exceed 15 ppm by weight. [R307-401-8]
- II.B.1.d.1 The sulfur content shall be determined by ASTM Method D2880-71, D4294-89, or approved equivalent. Certification of diesel fuel shall be either by the owner/operator's own testing or by test reports from the diesel fuel marketer. [R307-203-1]

- II.B.1.e The owner/operator shall maintain usage records of VOC emissions from the coating of products on medical devices on a rolling 12-month basis for UAC R307-350 and UAC R307-353. The owner/operator shall calculate a new 12-month total by the 20th day of each month using data from the previous 12 months. [R307-350-3, R307-353]

II.B.2 **VOC and HAPs Limitations**

- II.B.2.a The plant-wide emissions of VOCs or HAPs from the direct fabrication of medical devices and associated process lines, research and development activities, and laboratory activities (excluding the products of incomplete combustion from boilers, catalytic oxidizers, incinerators, regenerative thermal oxidizers, or internal combustion engines) shall not exceed:

23.85 tons per rolling 12-month period for VOCs

1.77 tons per rolling 12-month period for all HAPs combined

[R307-401-8]

- II.B.2.a.1 To determine compliance with a rolling 12-month total, the owner/operator shall calculate a new 12-month total quarterly, by the 20th day of January, April, July, and October using data from the previous 12 months. If for the previous period, total VOC and combined HAP emissions are greater than 75% of the above limits, the owner/operator shall calculate the 12-month total monthly, by the 20th day of each month, until total VOC and combined HAP emissions are less than 75% of the above limits for three (3) consecutive months. VOC and HAP emissions shall be determined by maintaining a record of VOC- and HAP-emitting materials used each month. The record shall include the following data for each material used:

- A. Name of the VOC- or HAPs-emitting material, such as: paint, adhesive, solvent, thinner, reducers, chemical compounds, toxics, isocyanates, etc.
- B. Density of each VOC- or HAPs-emitting material used (pounds per gallon)
- C. Maximum percent by weight of all VOC or HAP in each material used
- D. Gallons of each VOC- or HAP-emitting material used
- E. The amount of VOC or HAP emitted monthly from each material used. The amount of VOC or HAP emitted monthly by each material used shall be calculated by the following procedure:

$$\text{VOC} = (\% \text{ VOC by Weight})/100 \times [\text{Density (lb/gal)}] \times (\text{Gal Consumed}) \times (1 \text{ ton}/2000 \text{ lb})$$

$$\text{HAP} = (\% \text{ HAP by Weight})/100 \times [\text{Density (lb/gal)}] \times (\text{Gal Consumed}) \times (1 \text{ ton}/2000 \text{ lb})$$

- F. The total amount of VOC or HAP emitted monthly from all materials used
- G. The amount of VOCs or HAPs reclaimed for the month shall be similarly quantified and subtracted from the quantities calculated above to provide the monthly total VOC or HAP emissions.

[R307-401-8]

II.B.3 Catalytic Oxidation Limitations

- II.B.3.a The catalytic oxidation system shall control ethylene oxide emissions from the sterilization process. Emissions from each sterilization chamber shall be routed to the concentration-balancing tank, prior to being discharged to and processed by the desorption tower. Emissions from the concentration-balancing tank, desorption tower, and the aeration rooms shall be routed to the catalytic oxidizer before being discharged to the atmosphere. [R307-401-8]
- II.B.3.b At all times while operating any of the associated process lines, the owner/operator shall maintain a temperature at or above 140°C in the catalytic oxidizer catalyst bed. [40 CFR 63 Subpart O, R307-401-8]
- II.B.3.b.1 The owner/operator shall install, calibrate, maintain, and operate a device to monitor the operating temperature of the catalytic oxidizer in accordance with 40 CFR 63 Subpart O. The owner/operator shall maintain records as specified in 40 CFR 63 Subpart O. [40 CFR 63 Subpart O]

II.B.4 Thermal Incinerator Limitations

- II.B.4.a The thermal incinerator shall control emissions from process lines on the north side of the plant, including but not limited to, two (2) Push Button Blood Collection manufacturing lines (including spring winders), three (3) Nexiva Zone three (3) lines, and three (3) Autoguard manufacturing lines (including spring winders). All non-fugitive emissions from processes on the north side of the plant shall be routed through the thermal incinerator before being discharged to the atmosphere, except during periods of thermal incinerator bypass. [R307-401-8]
- II.B.4.b The sum of thermal incinerator bypass hours shall be minimized to the extent practicable to reduce emissions, not to exceed 96 hours per rolling 12-month period. [R307-401-8]
- II.B.4.b.1 To determine compliance with a rolling 12-month total, the owner/operator shall calculate a new 12-month total by the 20th day of each month using data from the previous 12 months. A record shall be maintained of the date, time, and reason when the thermal incinerator has been bypassed (during operation when venting uncontrolled process lines on the north side of the plant to the atmosphere). [R307-401-8]
- II.B.4.c At all times while operating any of the associated process lines, the owner/operator shall maintain a temperature at or above 1,400°F in the thermal incinerator. [R307-401-8]
- II.B.4.c.1 The owner/operator shall install, calibrate, maintain, and operate a device to monitor the operating temperature of the thermal incinerator. The monitoring device shall be located such that an inspector/operator can safely read the output at any time. The operating temperature of the thermal incinerator shall be recorded on a daily basis when any of the associated process lines are operating. [R307-401-8]

II.B.5 Regenerative Thermal Oxidizer Limitations

- II.B.5.a The Lesni regenerative thermal oxidizer shall control all non-fugitive emissions from process lines on the south side of the plant, including but not limited to, eight (8) Autoguard lines (including spring winders), and three (3) Nexiva manufacturing lines. All non-fugitive emissions from processes on the south side of the plant shall be routed through the regenerative thermal oxidizer before being discharged to the atmosphere, except during periods of regenerative thermal oxidizer bypass. [R307-401-8]

- II.B.5.b The Alliance Boxidizer regenerative thermal oxidizer shall control all non-fugitive emissions from three (3) Autoguard lines (including spring winders). All non-fugitive emissions from these processes shall be routed through the Alliance regenerative thermal oxidizer before being discharged to the atmosphere, except during periods of regenerative thermal oxidizer bypass. [R307-401-8]
- II.B.5.c The sum of regenerative thermal oxidizer bypass hours for each regenerative thermal oxidizer shall be minimized to the extent practicable to reduce emissions, not to exceed 96 hours per rolling 12-month period per regenerative thermal oxidizer. [R307-401-8]
- II.B.5.c.1 To determine compliance with a rolling 12-month total, the owner/operator shall calculate a new 12-month total by the 20th day of each month using data from the previous 12 months. A record shall be maintained of the date, time, and reason when either regenerative thermal oxidizer has been bypassed (during operation when venting uncontrolled process lines on the south side of the plant to the atmosphere). [R307-401-8]
- II.B.5.d At all times while operating any of the associated process lines, the owner/operator shall maintain the following temperatures:
- A. A temperature at or above 1,400°F in the Alliance Boxidizer regenerative thermal oxidizer
 - B. A temperature at or above 700°C in the Lesni regenerative thermal oxidizer
- [R307-401-8]
- II.B.5.d.1 The owner/operator shall install, calibrate, maintain, and operate a device to monitor the operating temperature of each regenerative thermal oxidizer. The monitoring device shall be located such that an inspector/operator can safely read the output at any time. The operating temperatures of each regenerative thermal oxidizer shall be recorded on a daily basis when any of the associated process lines are operating. [R307-401-8]
- II.B.6 **Curing Ovens**
- II.B.6.a The Filter Trains shall control emissions from the curing ovens. All non-fugitive emissions from these processes shall be routed through a filter train, which includes an electrostatic precipitator (installed on only one (1) filter train), a mist eliminator, a condensate blowout chamber, a coalescing filter, and finally a HEPA filter before being discharged to the atmosphere. [R307-401-8]
- II.B.7 **Cleaning Oven**
- II.B.7.a The thermal oxidizer shall control emissions from the attached cleaning oven. All emissions from this process shall be routed through the thermal oxidizer before being discharged to the atmosphere. [R307-401-8]

Section III: APPLICABLE FEDERAL REQUIREMENTS

In addition to the requirements of this AO, all applicable provisions of the following federal programs have been found to apply to this installation. This AO in no way releases the owner or operator from any liability for compliance with all other applicable federal, state, and local regulations including UAC R307.

NSPS (Part 60), A: General Provisions

NSPS (Part 60), IIII: Standards of Performance for Stationary Compression Ignition Internal Combustion Engines

MACT (Part 63), A: General Provisions

MACT (Part 63), O: Ethylene Oxide Emissions Standards for Sterilization Facilities

MACT (Part 63), ZZZZ: NESHAP for Stationary Reciprocating Internal Combustion Engines

PERMIT HISTORY

This AO is based on the following documents:

Supersedes	AO DAQE-AN103770009-16 dated December 15, 2016
Is Derived From	NOI dated December 19, 2017
Incorporates	NOI Addendum dated June 25, 2018
Incorporates	Additional Information dated July 10, 2018

ADMINISTRATIVE CODING

The following information is for UDAQ internal classification use only:

Salt Lake County

CDS B

MACT (Part 63), Nonattainment or Maintenance Area, NSPS (Part 60)

ACRONYMS

The following lists commonly used acronyms and associated translations as they apply to this document:

40 CFR	Title 40 of the Code of Federal Regulations
AO	Approval Order
BACT	Best Available Control Technology
CAA	Clean Air Act
CAAA	Clean Air Act Amendments
CDS	Classification Data System (used by EPA to classify sources by size/type)
CEM	Continuous emissions monitor
CEMS	Continuous emissions monitoring system
CFR	Code of Federal Regulations
CMS	Continuous monitoring system
CO	Carbon monoxide
CO ₂	Carbon Dioxide
CO ₂ e	Carbon Dioxide Equivalent - 40 CFR Part 98, Subpart A, Table A-1
COM	Continuous opacity monitor
DAQ/UDAQ	Division of Air Quality
DAQE	This is a document tracking code for internal UDAQ use
EPA	Environmental Protection Agency
FDCP	Fugitive dust control plan
GHG	Greenhouse Gas(es) - 40 CFR 52.21 (b)(49)(i)
GWP	Global Warming Potential - 40 CFR Part 86.1818-12(a)
HAP or HAPs	Hazardous air pollutant(s)
ITA	Intent to Approve
LB/HR	Pounds per hour
MACT	Maximum Achievable Control Technology
MMBTU	Million British Thermal Units
NAA	Nonattainment Area
NAAQS	National Ambient Air Quality Standards
NESHAP	National Emission Standards for Hazardous Air Pollutants
NOI	Notice of Intent
NO _x	Oxides of nitrogen
NSPS	New Source Performance Standard
NSR	New Source Review
PM ₁₀	Particulate matter less than 10 microns in size
PM _{2.5}	Particulate matter less than 2.5 microns in size
PSD	Prevention of Significant Deterioration
PTE	Potential to Emit
R307	Rules Series 307
R307-401	Rules Series 307 - Section 401
SO ₂	Sulfur dioxide
Title IV	Title IV of the Clean Air Act
Title V	Title V of the Clean Air Act
TPY	Tons per year
UAC	Utah Administrative Code
VOC	Volatile organic compounds